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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,014	02/29/2000	Patrick F. Coleman	09197-008810US	1609

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EXAMINER

BUDENS, ROBERT D

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 04/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.



APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2-4-02

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-14, 16-25 is/are pending in the application.
Of the above, claim(s) 13-14, 16-25 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-12 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☒ The specification is objected to by the Examiner.
- ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been:
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice to Comply with Sequence Rules
- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

The status of the related application(s) cited at the first page of the specification should be updated, if necessary, to ensure a properly completed file record.

5 The Examiner acknowledges Applicant's attempt to place the instant application in compliance with the Sequence Rules. However, Applicant's CRF was damaged and could not be read. The nature of the damage is unknown to the Examiner but it may have been due to the necessity of irradiating Applicant's submission for security purposes. A new copy of the CRF is required. See
10 attached Notice to Comply with Sequence Rules for additional information.

15 Applicant's election of Group I, claims 1-13 and the species BRU124F1X, in Paper No. 6, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse. See M.P.E.P. 818.03(a).

20 The Examiner acknowledges Applicant's Amendment, Paper No. 6, filed February 4, 2002. In view of Applicant's Amendment, the status of the claims is as follows: Claim 15 has been canceled; claims 13-14 and 16-25 have been withdrawn from consideration as being directed to a non-elected invention; Claims 1-12 are currently pending before the Examiner.

25 The Examiner acknowledges Applicant's submission of missing pages 24 and 25 of the specification. However, there is no copy of the receipt postcard confirming Applicant's original filing of these pages. In the absence of this evidence, the missing pages of the specification have not been entered in the file record. Applicant should submit a copy of the receipt postcard as evidence that the pages do not constitute NEW MATTER to the specification.
30 Upon receipt of convincing objective evidence, the Examiner will

consider entering the pages into the specification.

5 The application is objected to because of alterations which
have not been initialed and/or dated as is required by 37 C.F.R.
1.52(c) and 1.56. A properly executed oath or declaration which
complies with 37 CFR 1.67(a) and identifies the application by
serial number and filing date is required. Examples are at page 7,
line 25, reciting "1 + 10" and page 8, line 7, reciting "1 + 6."
Applicant is required to review the specification for any improper
changes/alterations and take appropriate action in response to this
10 Office Action.

15 A substitute specification is required in response to this
Office Action because the specification fails to comply with the
Sequence Rules and the necessary amendments for compliance would be
too extensive for entry in the file. The substitute specification
filed must be accompanied by a statement that it contains no new
matter. Such statement must be a verified statement if made by a
person not registered to practice before the Office.

The following is a quotation of the second paragraph of 35
U.S.C. 112:

20 **The specification shall conclude with one or more claims
particularly pointing out and distinctly claiming the subject
matter which the applicant regards as his invention.**

25 Claims 1-11 are rejected under 35 U.S.C. § 112, second
paragraph, as being indefinite for failing to particularly point
out and distinctly claim the subject matter which applicant regards
as the invention. Claim 1 is vague and indefinite in the
recitation "Z is OH or NH₂." since a claim cannot have a period in
the middle of the claim. Amendment of claim 1 to delete "." would
obviate this rejection. Claim 6 is vague and indefinite in the
30 recitation "substantially all" since it is entirely unclear how

much immunological reactivity would constitute "substantially all."
Amendment of claim 6 to delete "substantially" would obviate this
rejection.

The following is a quotation of the first paragraph of 35
U.S.C. § 112:

The specification shall contain a written
description of the invention, and of the manner and
process of making and using it, in such full, clear,
concise, and exact terms as to enable any person skilled
in the art to which it pertains, or with which it is most
nearly connected, to make and use the same and shall set
forth the best mode contemplated by the inventor of
carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph,
as containing subject matter which was not described in the
specification in such a way as to enable one skilled in the art to
which it pertains, or with which it is most nearly connected, to
make and/or use the invention. The claimed invention is directed
to methods using peptides of HIV "where oligopeptides having at
least six amino acids...will include epitopes within such sequence"
(see claims 1 and 12). Further, Applicant's claimed invention
encompasses peptides "modified by the substitution, addition or
deletion of amino acid residues" (see claim 6). However, the
specification does not set forth sufficient teachings to enable one
skilled in the art to identify and use such six amino acid
sequences with a reasonable expectation of success and without
undue experimentation. It is well known in the art that a
particular epitope varies from species to species and even within
the same species. Further, it is well known in the art that
modification of peptides such as Applicant's claimed peptides can
and often does abrogate antigenicity. In particular, modification
of as little as one amino acid can reduce or eliminate antibody
binding. Modification of immunological peptides is highly
unpredictable and Applicant has provided no guidance or working

examples to enable one skilled in the art to make such epitopes and modified proteins without undue experimentation. Applicant has attempted to claim any and all epitopes within a given sequence but has not set forth sufficient teachings to allow one skilled in the art to identify these epitopes without extensive trial and error, i.e., an invitation to experiment. Thus, the specification fails to enable the full scope of the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless--

- (b) the invention was patented or described in a printed publication in this country or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cosand et al., EP 0 267 802 (Applicant's AE). It is noted that the reference is listed on Applicant's Form PTO-1449 as having a publication date of March 4, 1998. However, this date is for publication of the application with mention of the grant of the patent. The publication date of the application is shown as May 18, 1988 and, hence, the reference is prior art to the instant application under 35 U.S.C. § 102(b).

Cosand et al. disclose peptides and oligopeptides and methods for detecting the presence of antibodies to HIV. Cosand discloses the peptide designated (IIa) (124) which is identical to the BRU124F1X peptide except that the BRU124F1X peptide is 10 amino acids longer (see Cosand et al., page 4, lines 45-51). However, since the oligopeptides of Cosand et al. can be 6 amino acids long

(see page 3, lines 27-29) which is identical to the "at least six amino acids" of the claimed peptides used in the claimed methods, Cosand et al. discloses to the public that which is claimed in the instant application and, inasmuch as this disclosure was made more than one year prior to the filing of this patent application, the issuance of a patent is barred.

No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.



Robert D. Budens
Primary Examiner
Art Unit 1648

rdh
April 22, 2002